UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

In re REPROS THERAPEUTICS, INC. SECURITIES LITIGATION

Civil Action No. 4:09-cv-02530

DEFENDANTS' REPLY IN SUPPORT OF THEIR MOTION TO DISMISS CONSOLIDATED CLASS ACTION COMPLAINT

Plaintiffs ask this Court to allow their securities fraud lawsuit to go forward despite basing that suit solely on an implausible inference entirely lacking in factual support. Plaintiffs suggest that Repros knew of poor results with the smaller doses of Proellex but disclosed negative information only about the larger, 50 mg dose, waiting 33 days to then disclose negative information about the smaller 25 and 12.5 mg doses, all so Repros could raise capital—which it never did. This inference is entirely implausible. Plaintiffs never explain why Repros would have disclosed the negative information on the larger dose if it was going to hide information on the smaller doses, or why, having embarked on a course of non-disclosure, Repros did not continue on that course until its supposed goal of raising capital was achieved. Far more plausible is the inference that Repros disclosed results as they were learned.

Moreover, Plaintiffs lack even a single fact—beyond the fact that a bad outcome occurred—on which to base their case. It is undisputed that Repros had substantial prior results on Proellex that were positive. It is likewise undisputed that additional clinical trials were ongoing and that Repros repeatedly cautioned that results from those trials might disagree with prior results. Finally, Plaintiffs do not even attempt to challenge the fact that Repros timely disclosed the negative results relating to the larger dose of Proellex. Having conceded all of this, Plaintiffs are left to nakedly assert that because further results for other dosing levels were poor,

those results must have been known earlier than actually disclosed. This is the sort of fraud-by-hindsight pleading that courts routinely reject.

Plaintiffs have no facts to support their claim and instead thrash around with various theories, including the contention that the raw data must have been available earlier, that it must have been reviewed earlier, and that such a review must have revealed the liver enzymes issue with the smaller doses. Plaintiffs' assertion that all of those events must have happened, however, does not equal any support for such a claim, particularly given that Repros disclosed other results from the same ongoing trials only a month before. Ultimately, even Plaintiffs concede the legitimacy of this position, noting that "[i]t is possible that Defendants could receive unexpected data about elevated liver enzymes associated with Proellex, and it would take Defendants 33 days to analyze the data and confer with experts to determine the extent of the liver issues, and ascertain whether those problems were also present in the lower doses." (Opp. 13-14.) This is not only possible—it is the only inference that is remotely plausible in this case. For that reason, the Complaint should be dismissed.

I. ARGUMENT

A. The Complaint Lacks Facts to Support Either Falsity or Scienter.

To survive dismissal under the Private Securities Litigation Reform Act ("PSLRA"), a complaint must include particularized, nonconclusory allegations demonstrating that statements made by the defendants were false or misleading, as well as facts giving rise to a strong inference that the defendants acted with scienter at the time the statements were made. Absent such allegations, a plaintiff cannot meet either the falsity or scienter element of a securities fraud claim under Section 10(b) and Rule 10b-5. *E.g., Ind. Elec. Workers' Pension Trust Fund IBEW v. Shaw Group, Inc.*, 537 F.3d 527, 532-33 (5th Cir. 2008).

The case law cited by Plaintiffs demonstrates the sort of facts required to plead falsity and scienter. In all of those cases, the plaintiffs had far more than an assertion that bad facts must have been known. To the contrary, the plaintiffs were able to point to particularized facts for a claim that information was both known and withheld:

- In *In re Connetics Corp. Securities Litigation*, plaintiffs alleged that defendants failed to disclose a study that resulted in cancerous skin tumors in 89 out of 160 mice and that defendants "concealed the results of this study from investors and analysts for almost a full year, continuing to tout [the drug's] safety." No. C 07-02940 SI, 2008 WL 3842938, at *1, *6 (N.D. Cal. Aug. 14, 2008). The complaint also alleged that defendants failed to disclose that their own panel of experts had warned that they knew of no drug with similar results that had ever been approved by the FDA. *Id*. at *7.

- In *In re Regeneron Pharmaceuticals, Inc. Securities Litigation*, the complaint contained allegations from over 20 former employees of the company to the effect that defendants knew of but failed to disclose a significant antibody problem with the drug. No. 03 Civ. 3111 RWS, 2005 WL 225288, at **19-20 (S.D.N.Y. Feb. 1, 2005).[1]

- The complaint in *In re Amylin Pharmaceuticals, Inc. Securities Litigation* quoted minutes of a meeting between the company and the FDA during which the FDA expressed doubts about the company's testing methodology. No. 01CV1455 BTM (NLS), 2003 WL 21500525, at *1, *5 (S.D. Cal. May 1, 2003). The Court denied a motion to dismiss, finding that the minutes were sufficient to allege falsity as to the company's statements—made *after* the FDA meeting—that its tests were sufficient to support FDA approval. *Id*. at *1, *9.

Plaintiffs lack such factual allegations here. Plaintiffs allege no evidence that anyone at Repros was aware of negative data before it was actually disclosed. They can point to no studies, data, documents, meeting minutes, or any other similar items to support the claim that knowledge of the liver enzymes issue with the lower doses existed before the issue was disclosed. This absence of a factual basis is hardly surprising, given the undisputed fact of prior

[1] The other *Regeneron Pharmaceuticals* case cited by Plaintiffs is a summary judgment case having nothing to do with pleading standards. *In re Regeneron Pharms. Sec. Litig.*, No. 94 CIV. 1785 (CLB), 1995 WL 228336, at *1 (S.D.N.Y. Mar. 10, 1995).

positive results and the undisputed fact that Repros timely disclosed the liver enzymes issue with the 50 mg dose of Proellex.

The best that Plaintiffs can do is attack the July 1 Press Release because it "says nothing about an increase in liver enzymes at the 25 mg and 12.5 mg, and the implication is there is none." (Opp. 9.) Of course, that press release expressly references the fact that studies of the product were "ongoing" and that further studies would still take place. (Mot. Ex. 6.) On July 7, Repros confirmed that the then-available data did not show an increase in liver enzymes at the smaller doses. Specifically, the July 7 press release stated that, of the 470 patients treated with Proellex, only 10 had discontinued treatment due to an increase in liver enzymes. (Mot. Ex. 7.) One of the ten was on the 25 mg dose, but that patient had a possible pre-existing condition that might have affected her results. (*Id.*) No patient on the 12.5 mg dose discontinued treatment due to elevated liver enzymes. (*Id.*) Based on this data, Repros indicated its belief that the 25 and 12.5 mg doses ultimately "will offer comparable efficacy benefits while providing an improved safety profile." (*Id.*) Plaintiffs offer no reason why Repros should not have relied on this data and no explanation as to how this data contradicts the July 1 press release or any other public statement of the Company. Nor do they address the fact that Repros never suggested that all of the trials were complete or that further data and analysis would not yield different results. Indeed, Plaintiffs "do not dispute that clinical trials can produce unexpected and disappointing results." (Opp. 10.[2]) That is exactly what happened here. Defendants disclosed data, both good and bad, as it became available.

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[2] The Opposition implies that Defendants were reckless in issuing *any* information about the available data on the lower doses simply because it was not final. (Opp. 13-14.) This is nothing more than an argument that Defendants were reckless because the continuing trials provided different results or, stated differently, an impermissible claim of fraud-by-hindsight. *See Lormand v. US Unwired, Inc.*, 565 F.3d 228, 254 (5th Cir. 2009) (describing the classic "fraud by hindsight" scenario as one in which "a plaintiff alleges that the fact that something turned out badly must mean defendant knew earlier that it

In sum, Plaintiffs have pleaded no facts showing that any Defendant knew anything about the liver enzymes issues contrary to what was disclosed in the company's press releases, nor have they pleaded any facts indicating that any Defendant knew about elevated liver enzymes at any time before press releases disclosed the issue. Absent such facts, the Complaint fails to plead the elements of falsity and scienter, and should be dismissed under Rules 9(b) and 12(b) of the Federal Rules of Civil Procedure and the PSLRA.

B. Neither the Individual Defendants' Positions as Officers of Repros nor the Small Size of the Company Gives Rise to a Strong Inference of Scienter.

Defendants moved to dismiss on scienter, among other grounds. (Mot. 10-20.) Lacking any particularized facts demonstrating that Defendants actually knew that their statements were false or misleading, Plaintiffs resort to *Nathenson v. Zonagen Inc.*, 267 F.3d 400 (5th Cir. 2001), a very narrow case defining when, for scienter purposes, knowledge of bad facts may be imputed to corporate officers and directors. (Opp. 15-17.) But *Nathenson* does not go nearly as far as Plaintiffs say, and more importantly, it is plainly distinguishable because in this case there are no particularized bad facts at all, much less bad facts that can be imputed to Defendants.

In *Nathenson*, the Fifth Circuit reaffirmed the longstanding rule that "an officer's position with a company does not suffice to create an inference of scienter." 267 F.3d at 424. The court went on to hold, however, that the facts of that case presented a collection of "special

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would turn out badly") (citation omitted). Surely Plaintiffs are not suggesting that Defendants were reckless in keeping their investors informed concerning the status of clinical trials. Plaintiffs cite no authority for their novel proposition because there is none. In fact, such trials take months or even years to complete, and pharmaceutical companies engaged in the development of new drugs routinely make statements regarding interim data and/or results associated with their clinical trials. *See, e.g.*, *Heywood v. Cell Therapeutics, Inc.*, No. C05-0396RSM, 2006 WL 5701625, at **4-5 (W.D. Wash. May 4, 2006) (granting motion to dismiss where plaintiffs alleged that defendants' statements regarding interim results were misleading); *DeMarco v. DepoTech Corp.*, 149 F. Supp. 2d 1212, 1226-27 (S.D. Cal. 2001) (discussing statements related to interim clinical trial results in 10(b) case ultimately dismissed with prejudice).

circumstances" that sufficed—"if perhaps only barely so"—to support the requisite inference of scienter with respect to the CEO's knowledge of the falsity of Zonagen's statement that it had acquired rights to a patent covering its new drug. *Id.* at 425. Those circumstances were: (1) Zonagen was "essentially a one product company," and its SEC filings indicated that substantially all of its efforts and expenditures over the next several years would be devoted to that drug; (2) patent protection was important to the company, and its ability to compete effectively would depend on the proprietary nature of its patents and technologies; (3) the company had acquired the patent rights in question two years before the misstatement, allowing ample opportunity to become familiar with them; (4) the company was small, with less than forty employees; and (5) the officer in question had made public statements indicating that the company's patent did not cover the drug. *Id*.

The *Nathenson* court articulated no sweeping rule; to the contrary, the opinion was expressly limited to what the court viewed as unique facts. Indeed, the central fact to the court's decision was that a simple reading of the touted patent would have revealed that it did not, in fact, cover the company's drug. *See id*. at 422-23, 425. As such, the existence of "bad facts"—the information contrary to what the company disclosed—was alleged with particularity and was not in dispute. The only issue was whether the officer could be charged with knowledge of what the patent meant or did not mean.

In stark contrast, Plaintiffs here can point to no facts that contradict Repros' public statements. Whereas the falsity of the statement in *Nathenson*—that a patent covered the company's new drug—would have been known by simply reading the patent that indisputably existed and was available to the officer in question, the Complaint in this case contains no allegation that raw data existed in any sort of reviewable form or that the Defendants would have

known of the allegedly misleading nature of Repros' public statements merely by reviewing such data. Moreover, unlike the Zonagen officer who had more than two years to learn about the patent before the false statement was made, Plaintiffs admit that Proellex trials, including those in which the liver enzymes issues were discovered, were ongoing during the class period. Accordingly, *Nathenson* does not support an inference of scienter here.[3]

C. Repros' Financing Needs Do Not Give Rise to a Plausible, Let Alone Strong, Inference of Scienter.

At the end of the day, Plaintiffs are left with little more than an allegation that Repros' financing needs gave the Defendants a "motive to conceal the truth about elevated liver enzymes, at least in the short term, to maximize their chances of receiving essential funding and extend the License Agreement." (Opp. 17.) This financial motive theory, however, is both legally and factually flawed.

As Defendants pointed out in their motion to dismiss, courts routinely recognize that the motivation to raise capital is the quintessential motive universal to corporate executives that does not give rise to a strong inference of scienter. (*See* Mot. 17-18 & n.7 (citing *Shaw Group*, 537 F.3d at 544; *Cozzarelli v. Inspire Pharms. Inc.*, 549 F.3d 618, 622, 627 (4th Cir. 2008); *In re Vertex Pharms. Inc., Sec. Litig.*, 357 F. Supp. 2d 343, 351, 354 (D. Mass. 2005); *In re Discovery Labs Sec. Litig.*, No. 06-1820, 2006 WL 3227767, at *14 (E.D. Pa. Nov. 1, 2006)).)

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[3] Plaintiffs point to the fact that Dr. Lammers and Mr. Ploth left the Company after Repros cancelled all Proellex trials as "additional evidence of scienter." (Opp. 15 n.5.) The Fifth Circuit, however, does not recognize a subsequent resignation by a corporate official as creating an inference of scienter. *Southland Sec. Corp. v. INSpire Ins. Solutions, Inc.*, 365 F.3d 353, 383 (5th Cir. 2004) ("[B]ecause fraud cannot be proved by hindsight, . . .[t]he subsequent resignations of INSpire executives is . . . unavailing as proof of the commission of fraud by these or other individuals."). Further, the Complaint does not allege any facts to support Plaintiffs' insinuation that Dr. Lammers' and Mr. Ploth's resignations were in any way related to the alleged misstatements. *See Branca v. Paymentech, Inc.*, No. Civ. A. 3:97-CV-2507-L, 2000 WL 145083, at *11 (N.D. Tex. 2000) (mem. op.) ("Plaintiffs cannot adequately raise an inference of scienter by relying on the fact that Truetzel resigned at the end of the class period. . . . While it is clear that Plaintiffs wish to imply that Truetzel's departure was related to his alleged accounting malfeasance, they have pleaded no facts whatsoever to support this inference. These allegations simply do not support any inference of scienter.").

Plaintiffs' efforts to distinguish Defendants' cases are unavailing. For example, Plaintiffs argue that *Vertex* is distinguishable because the alleged misstatements at issue in that case "involved one drug of many that the company was developing and intended to bring to market," whereas "Proellex was Repros' key, 'make or break' product." (Opp. 18 n.7.) That argument—which was not made by the *Vertex* court itself in rejecting the plaintiff's financial motive theory of scienter—completely ignores the fact that the drug at issue in *Vertex* was the company's "leading market candidate," as well as the fact that the Vertex executives had a much more significant financial incentive to delay release of adverse information about the drug—namely, a pending merger valued at $529 million. 357 F. Supp. 2d at 346, 351-53.

Similarly, Plaintiffs assert that *Discovery Labs* is distinguishable because the $8 million in equity financing that the company was seeking to close "was not needed for the survival of the company," whereas the ability to obtain financing was "crucial to Repros' survival." (Opp. 18 n.7.) Again, however, that is Plaintiffs' own gloss on the case. Nothing in the opinion itself indicates that the $8 million in equity financing raised by Discovery Labs—"a small biotechnology company" that had "no product on the market"—was not critical to the company, nor did the court even mention the allegedly non-essential nature of the financing in rejecting the plaintiff's financial motive theory. 2006 WL 3227767, at *1, *14.

Nor do the cases cited by Plaintiffs (*see* Opp. 18-19) support their financial motive theory. For example, although Plaintiffs assert that the Fifth Circuit held in *Goldstein v. MCI WorldCom* that "the plaintiffs' allegations of the company's need to complete a 'crucial' merger were sufficient to plead motive" (Opp. 19), the court actually went on to hold that, notwithstanding the defendants' motive to withhold negative information in order to close the merger, the plaintiffs' allegations were *insufficient* to raise a strong inference of scienter. 340

F.3d 238, 249-54 (5th Cir. 2003) ("[T]he plaintiffs' motive allegations, without more than is found in this complaint, are insufficient to satisfy the 'strong inference of scienter' requirement."). Nor did the Fifth Circuit hold in *Nathenson* that the "dependence of a company's future prospects on the success of a potential drug supports a strong inference of scienter," as Plaintiffs contend. (Opp. 18-19.) Instead, the court merely treated the company's dependence on the drug's success as one factor supporting an inference that the defendants knew, by virtue of their positions with the company, that the drug was not covered or protected by the company's key patent. 267 F.3d at 422-24. More importantly, the *Nathenson* court specifically rejected the plaintiffs' claim that the defendants had a financial motive to make misleadingly positive statements about the company's Phase III clinical trial results, holding that those allegations did not give rise to the strong inference of scienter necessary to support a fraud claim based on statements concerning the Phase III trials. *Id.* at 419-20. Thus, both *Goldstein* and *Nathenson* support Defendants' argument that Plaintiffs' allegations regarding a financial incentive to withhold negative information about Proellex are insufficient to create a strong inference of scienter.

Moreover, even if Plaintiffs' financial motive theory were legally tenable, it still fails to support a strong inference of scienter because it is factually implausible. According to Plaintiffs, Defendants revealed the liver enzymes issue with the 50 mg dose, but hid problems with the 25 and 12.5 mg doses on July 1 in order to secure the July 7 NIH Amendment, which did not provide Repros with financing but rather imposed on Repros an obligation to raise $6 million by September 30. Repros purportedly then revealed some more information about the liver enzymes issue with the higher dose of Proellex, but continued to hide problems with the lower doses on July 7 and July 23 in order to keep the company afloat long enough to raise the

necessary funds by September 30. But then, on August 3—almost two months before the September 30 deadline and without having raised any capital at all—Defendants decided to reveal the full extent of the liver enzymes issues with Proellex.

Plaintiffs' theory is not even plausible. It makes no sense that Defendants would partially reveal the liver enzymes issue if they were motivated to commit fraud in order to raise "critical" capital. It also makes no sense that Defendants would shortly thereafter reveal the rest of the liver enzymes issues, allegedly hidden to date due to the supposed motivation to commit fraud to raise capital, before Defendants actually raised capital and before the deadline to raise capital had even expired.

The facts of this case—and the timing of the events during the Class Period in particular—belie Plaintiffs' assertion that "[t]he unique timing of Repros's eleventh-hour financing attempt" gives rise to "a compelling inference of scienter." (Opp. 19.) And because courts consistently reject the argument that even successful capital raising efforts can give rise to an inference of scienter, it is not surprising that Plaintiffs cite no cases suggesting that an unfulfilled desire to raise capital can give rise to an inference of scienter. The only logical inference, and certainly the more persuasive one, is that Defendants disclosed negative information as it became available, without any regard for the company's capital needs.

II. CONCLUSION

For these reasons, Defendants respectfully request that the Court dismiss Plaintiffs' amended Consolidated Complaint, with prejudice, for failure to state a claim.

Respectfully submitted,

/s/ David D. Sterling
David D. Sterling
Fed. I.D. No. 07079
Texas Bar No. 19170000
BAKER BOTTS L.L.P.
One Shell Plaza
910 Louisiana Street
Houston, Texas 77002
Telephone: 713.229.1946
Facsimile: 713.229.7946
david.sterling@bakerbotts.com

ATTORNEY-IN-CHARGE FOR DEFENDANTS

OF COUNSEL:

Samuel Cooper
Fed. I.D. No. 19954
Texas Bar No. 00792427
Tracy N. LeRoy
Fed. I.D. No. 860752
Texas Bar No. 24062847
Amy Pharr Hefley
Texas Bar No. 24046046
BAKER BOTTS L.L.P.
One Shell Plaza
910 Louisiana Street
Houston, Texas 77002
Telephone: 713.229.1234
Facsimile: 713.229.1522

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing document was served electronically on all counsel of record on this 10th day of May, 2010.

/s/ David D. Sterling
David D. Sterling